American Medical Systems, Inc.
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JUN 14 1996

American Medical Systems

K961887

SUMMARY OF SAFETY AND EFFECTIVENESS

I. SUBMITTER

Name and Address:	American Medical Systems, Inc. 10700 bren Road West Minnetonka, MN 55343
Contact Person:	Lisa L. Pritchard
Date of Summary Preparation:	April 23, 1996
Establishment Registration Number:	2183959

II. DEVICE NAME

Device Common or Usual Name:	Artificial Urinary Sphincter
Device Trade Name:	AMS Sphincter 800™ Urinary Prosthesis

III. PREDICATE DEVICE

Implanted Mechanical/Hydraulic Urinary Continence Device

IV. DEVICE DESCRIPTION

The AMS Sphincter 800™ Urinary prosthesis is a three component system designed to maintain continence by applying minimal pressure around the circumference of the bladder neck or bulbous urethra. The device is totally implanted.

The device is made of solid silicone elastomer and consists of a control pump, a pressure regulating balloon and an occlusive cuff. The pump is implanted in subcutaneous tissue of the scrotum or labia. the pressure regulating balloon is inserted into the prevesical space. The cuff is totally implanted around the bulbous urethra or bladder neck. Fluid in the cuff exerts an occlusive force on the urethra. By depressing the control pump bulb, fluid moves from the cuff back to the pressure regulating balloon, allowing the patient to void. Fluid travels slowly back to the cuff which will restore continence.

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American Medical Systems is proposing to modify the poppet housing and tubing socket of the control pump. The modifications are being made to improve the performance of the device and to improve its' manufacturability.

V. INDICATION FOR USE

The AMS Sphincter 800™ Urinary Prosthesis is an implantable, fluid-filled, solid silicone elastomer device used to treat urinary incontinence caused by Intrinsic Sphincter Deficiency (ISD). The AMS Sphincter 800 is implanted in men, women, and children.

VI. COMPARISON TO PREDICATE DEVICE

The Sphincter 800™ Urinary Prosthesis with the proposed pump modifications is substantially equivalent to the current Sphincter 800™ Urinary Prosthesis in commercial distribution.

a. Intended Use

The AMS Sphincter 800™ Urinary Prosthesis with the modified pump has the same intended use as the standard AMS Sphincter 800™ Urinary Prosthesis. This product is an implantable, fluid-filled, solid silicone elastomer device used to treat urinary incontinence caused by Intrinsic Sphincter Deficiency (ISD). The AMS Sphincter 800 prosthesis is implanted in men, women, and children.

b. Principles of Operation

In both the current and modified pumps, the patient squeezes the pump mechanism, located in the scrotum or labium, several times to move fluid from the cuff to the pressure regulating balloon located in the abdomen. Fluid gradually flows back into the cuff, restoring continence after a few minutes. Pressure in the cuff is maintained at a nearly constant level by a pressure regulating balloon.

c. Device Performance

The Sphincter 800 Urinary Prosthesis with modified pump is comparable with respect to intended use and technological characteristics to the Sphincter 800™ Urinary Prosthesis which is in commercial distribution in the United States. American Medical Systems has provided a table comparing the similarities and differences of the lubricated pump to the standard pump.

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d. Bench Testing

American Medical Systems has provided descriptive data on the test plan and test results for the modified Sphincter 800 pump. These data support that the function and characteristics of the device are suitable for its intended use.

In summary, American Medical Systems has provided information within the 510(k) Premarket Notification to indicate that the Sphincter 800™ Urinary Prosthesis with modified pump is safe and effective for its intended use in the treatment of urinary incontinence. Additionally, the modified Sphincter 800 pump has been shown to be comparable in terms of intended use and technological characteristics to the standard Sphincter 800 pump currently in commercial distribution. The data and information provided within this 510(k) premarket notification adequately support that the Sphincter 800 Urinary Prosthesis with modified pump is substantially equivalent to the Sphincter 800 Urinary Prosthesis with standard pump currently in commercial distribution.